

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
) SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
) AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8630

Bartle, C.J.

March 31, 2011

Mary Dickinson ("Ms. Dickinson" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. James T. Dickinson, Ms. Dickinson's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In January, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Azam Ansari, M.D. Dr. Ansari is no stranger to this litigation. According to the Trust, Dr. Ansari has signed in excess of 163 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated September 9, 2002, Dr. Ansari attested in Part II of Ms. Dickinson's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension,

3. (...continued)

presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

and a reduced ejection fraction in the range of 50% to 60%.⁴

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$518,044.⁵

In the report of claimant's echocardiogram, Dr. Ansari stated that "[t]here was moderate mitral regurgitation, which occupied 20% of the left atrial surface area." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2003, the Trust forwarded the claim for review by Fadi Chaaban, M.D., one of its auditing cardiologists. In audit, Dr. Chaaban concluded that there was no reasonable medical basis for the attesting physician's finding of moderate

4. Dr. Ansari also attested that claimant suffered from mild aortic regurgitation. As Ms. Dickinson's claim does not present any of the complicating factors necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a). Dr. Ansari further attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral regurgitation.

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Dickinson's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a supplemental opinion from Dr. Ansari, who confirmed his finding of moderate mitral regurgitation and attached still frames from claimant's September 9, 2002 echocardiogram that purportedly demonstrated moderate mitral regurgitation. Claimant also argued that: (1) the auditing cardiologist selectively downgraded her level of mitral regurgitation from moderate to mild; (2) the auditing cardiologist only visually assessed her level of mitral regurgitation; (3) the Green Form does not have the same answer choices as the Auditor's Report; and (4) the Trust failed to specify the auditing cardiologist's credentials in connection with its denial.⁷

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Dickinson's claim.

7. The Trust provided claimant with Dr. Chaaban's credentials with its final post-audit determination.

The Trust then issued a final post-audit determination, again denying Ms. Dickinson's claim. With its determination, the Trust included a supplemental declaration prepared by the auditing cardiologist, Dr. Chaaban, who was asked to review Ms. Dickinson's claim for a second time. In his supplemental declaration, Dr. Chaaban again concluded that claimant had only mild mitral regurgitation. In support of this conclusion, Dr. Chaaban explained that:

The freeze-frame images upon which Claimant's Attesting Physician relies are not seen in real time on the tape. Moreover, the planimetry upon which Claimant's Attesting Physician relies inflates the regurgitant jet area ("RJA") to left atrial area ("LAA") ratio by overtracing the RJA to include low velocity, nonregurgitant flow and by understating the LAA.

Claimant's true RJA/LAA ratio is less than 15%.

Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § IV.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Dickinson's claim should be paid. On September 27, 2004, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 3992 (Sept. 27, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting

documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 8, 2004, and claimant submitted a sur-reply on January 8, 2005. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

In support of her claim, Ms. Dickinson mainly reasserts the arguments that she made in contest. Claimant also provides another opinion from Dr. Ansari, in which he reiterates his finding of moderate mitral regurgitation and attaches still frames from claimant's echocardiogram. Claimant also criticizes the Trust's administration of claims and argues that the audit process is unfair to claimants.

In response, the Trust argues that there is no reasonable medical basis for Ms. Dickinson's claim because the auditing cardiologist found that the attesting physician improperly overtraced claimant's regurgitant jet to include low velocity flow. The Trust also contends that the auditing cardiologist complied with the Settlement Agreement in assessing claimant's level of mitral regurgitation. Finally, the Trust argues that the additional possible responses included in the Report of the Auditing Cardiologist have no effect on the outcome of claims, and that claimant's criticisms of the Trust's administration of claims are beyond the scope of the show cause proceedings.

In her sur-reply, claimant argues that the Trust cannot modify the definition of mitral regurgitation by referencing "low velocity" flow. Claimant also asserts that there is a reasonable

medical basis for her claim because Dr. Ansari participated in the Trust's Screening Program.⁹ Finally, claimant contends that the Trust has failed to produce "verifiable evidence" to support its denial of her claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

Only mild mitral regurgitation was seen in all views. There was only trace mitral regurgitation noted in the parasternal long axis view. In both the apical four and two chamber views, only mild mitral regurgitation was noted with a central jet slightly above the coaptation point of the mitral leaflets. The RJA/LAA ratio was less than 15%. In comparing the real-time images with the submitted still frames, it is clear that the "computerized measurement" of the supposed [mitral regurgitant] jet was wrong. Low velocity non-[mitral regurgitant] flow was included in this measurement. The RJA/LAA ratio does not come close to reaching 20%.

In response to the Technical Advisor Report, claimant argues that Dr. Vigilante failed to provide exhibits or illustrations substantiating his findings. Claimant also contends that Dr. Vigilante altered the Green Form definition of

9. See Settlement Agreement § IV.A.1 (Fund A screening program established under the Settlement Agreement).

mitral regurgitation by referencing low velocity flow in his analysis.¹⁰

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that Dr. Vigilante did not substantiate his finding or that the auditing cardiologist's findings lack verifiable evidence. To the contrary, the auditing cardiologist identified a specific deficiency with Dr. Ansari's measurements; namely, that he "overtrac[ed] the RJA to include low velocity, nonregurgitant flow."¹¹ Similarly, Dr. Vigilante concluded that Dr. Ansari improperly included "[l]ow velocity non- [mitral regurgitant] flow" in his measurements. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.¹²

Further, we disagree with claimant that low velocity flow is considered mitral regurgitation. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and

10. Claimant additionally contends that Dr. Vigilante lacks the necessary credentials to be a Technical Advisor as set forth in Audit Rule 32. We disagree. We appointed Dr. Vigilante to assist the court in reviewing certain claims in the show cause process after finding that he possessed the requisite skills and expertise. See PTO No. 3212 (Jan. 14, 2002).

11. The auditing cardiologist, therefore, did not selectively downgrade claimant's level of mitral regurgitation from moderate to mild.

12. For these reasons as well, the still frames submitted by claimant are insufficient to establish a reasonable medical basis for her claim.

still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Chaaban and Dr. Vigilante concluded that Dr. Ansari improperly included low velocity flow in his measurements of claimant's mitral regurgitation. Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer of moderate mitral regurgitation.

Moreover, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See id. at 15. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a

revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

We also disagree with claimant's assertion that the Trust's audit system is unfair to claimants. It is claimant's burden in the show cause process to show why she is entitled to Matrix Benefits. See Audit Rule 24. The audit and show cause process, as approved by this court, provide claimant with notice and an opportunity to present her evidence in support of her claim.¹³ Claimant has not presented any evidence that the audit of her claim was not done in an objective manner. We, therefore, reject claimant's challenge to the audit process.

Finally, we reject claimant's assertion that she is entitled to Matrix Benefits because Dr. Ansari, who participated in the Trust's Screening Program, determined her echocardiogram demonstrated moderate mitral regurgitation. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit that an eligible class member is entitled to receive for an echocardiogram performed in the Screening Program is a limited amount of medical services or a limited cash payment:

13. We also reject claimant's argument that there are inconsistencies between the possible answers on the Green Form and the Auditor's Report. Although the Auditor's Report includes additional selections for the level of mitral regurgitation and ejection fraction, these choices have no bearing on whether a claimant is eligible for Matrix Benefits.

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Settlement Agreement, § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants with a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with Section VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See PTO No. 2662 at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A benefits results in an immediate entitlement to Matrix Benefits, or that a cardiologist's participation in the Screening Program entitles his or her opinion to more weight, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Dickinson's claim for Matrix Benefits and the related derivative claim submitted by her spouse.